**Minutes of the**
**United States Environmental Protection Agency (EPA)**
**Human Studies Review Board (HSRB)**
**December 16, 2009 Public Teleconference Meeting**
**Docket Number: EPA-HQ-ORD-2009-0891**
**HSRB Web Site: http://www.epa.gov/osa/hsrb**

Committee Members: (See EPA HSRB Members list – Attachment A)

| | | |
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| Date and Time: | Wednesday, December 16, 2009, 10:00 AM – 12:00 Noon (See *Federal Register* Notice – Attachment B) | |
| Location: | via teleconference | |
| Purpose: | The EPA Human Studies Review Board provides advice, information, and recommendations on issues related to the scientific and ethical aspects of human subjects research. | |
| Attendees: | Chair: | Sean Philpott, Ph.D., M.S. Bioethics |
| | Vice Chair: | Janice Chambers, Ph.D., D.A.B.T. |
| | Board Members: | Suzanne C. Fitzpatrick, Ph.D., D.A.B.T.<br>Sidney Green, Jr., Ph.D., Fellow, ATS<br>Dallas E. Johnson, Ph.D.<br>Michael D. Lebowitz, Ph.D., FCCP<br>Lois D. Lehman-McKeeman, Ph.D.<br>William J. Popendorf, Ph.D.<br>Linda J. Young, Ph.D. |
| Meeting Summary: | Meeting discussions generally followed the issues and general timing as presented in the meeting Agenda (Attachment C), unless noted otherwise in these minutes. | |

## INTRODUCTORY REMARKS, MEETING ADMINISTRATIVE PROCEDURES, AND MEETING PROCESS

Mr. Jim Downing (Designated Federal Officer [DFO], Human Studies Review Board (HSRB), Office of the Science Advisor [OSA], U.S. Environmental Protection Agency [EPA or Agency]) opened the teleconference meeting and welcomed Board members, EPA staff, and members of the public to the call. He acknowledged and thanked Board members for their efforts in preparing for and deliberating at HSRB meetings and teleconferences. The purpose of this teleconference meeting was to review the decisions made by the Board at the October 2009 HSRB meeting and to finalize the Board report from that meeting.

As DFO, Mr. Downing serves as liaison between the HSRB and EPA and ensures that Federal Advisory Committee Act (FACA) requirements—open meetings, timely meeting

announcements in the *Federal Register*, and meeting materials made available at a public docket—are met. As DFO, he also works with the appropriate officials to ensure that all applicable ethics regulations are satisfied. Each Board member has filed a standard government financial disclosure form that has been reviewed by Mr. Downing and the OSA Deputy Ethics Officer in consultation with EPA's Office of General Counsel to ensure that all ethics disclosure requirements have been met. Mr. Downing reminded participants that meeting times would be approximate and that public comments would be limited to 5 minutes.

According to FACA requirements, meeting minutes including descriptions of the discussions and conclusions reached by the Board will be prepared. These minutes will be certified by the chair within 90 days of the meeting and posted at www.regulations.gov and on the HSRB Web site. The Board members also will finalize the October 2009 meeting report; completion and approval of this report will be announced in the *Federal Register*.

Dr. Sean Philpott explained that the Board would discuss its response to each charge question and summarize conclusions. For each question, Board members will have an opportunity to raise concerns they may have about Board conclusions and rationales.

Because this was her last HSRB meeting, Dr. Philpott acknowledged Dr. Lois Lehman-McKeeman's service to the Board and thanked her for her insightful comments and recommendations. Mr. Downing and Mr. William Jordan (Office of Pesticide Programs [OPP], EPA) added their thanks on behalf of the Agency.

## PUBLIC COMMENTS

Dr. Philpott invited public comment on the draft October 20-21, 2009 HSRB meeting report. No public comments were presented.

## BOARD DISCUSSION AND DECISION ON REPORT

**Assessment of Completed Research Study: Newton, J., Breslin, A. (1983) Asthmatic reactions to a commonly used aerosol insect killer. *Medical Journal of Australia* 1:378-380.**

Dr. Philpott opened discussion of the Board's conclusions regarding the Newton and Breslin study. This was a completed study in which seven participants with a history of asthma were evaluated for asthmatic reactions after exposure to an aerosol insecticide spray containing pyrethrins/pyrethroids. The Board responded to several charge questions posed by the Agency for this study.

Regarding the first charge question, whether the Newton and Breslin study was likely to yield scientifically sound, reliable data, the Board concluded that the study was of limited utility. Dr. Philpott inquired if Board members had comments on the Board's response to the charge question. No changes were suggested.

The second charge question asked the Board to evaluate whether this study was relevant to an assessment of the association of pyrethrin/pyrethroid exposure and asthmatic or allergic

respiratory responses. The Board concluded that this study was relevant only for the specific product tested because it constituted a mixture of substances, rather than pure pyrethroid/pyrethrin. Dr. William Popendorf suggested that the last sentences of the Board's response to this charge be changed to better reflect the chemically complex nature of the insecticide product used. Dr. Lehman-McKeeman suggested replacing "complex" with the statement, "...a complex mixture represented by an insecticide product, rather than a specific chemical." Board members agreed to this change.

The third charge question asked the Board to consider limitations of the Newton and Breslin study for its use in assessing the association between pyrethrins/pyrethroids and asthmatic or allergic responses. Dr. Philpott suggested replacing "complex insecticide product" with Dr. Lehman-McKeeman's phrase proposed for the second charge question. The Board members agreed with the change.

Mr. John Carley (OPP, EPA) relayed a comment from the EPA Health Effects Division regarding the Board's detailed recommendations and rationale for the Newton and Breslin study. In the second paragraph, the citation ("EPA Office of Pesticide Programs 2009") in the second sentence is incorrect. He also suggested deleting the sentence entirely or replacing it with a sentence acknowledging that when a mixture of ingredients is tested, effects cannot be attributed to a single ingredient. Dr. Philpott explained that the Board was not asked to address this issue in the charge question and that some of the chemicals in the mixture are potential respiratory allergens. He recognized EPA's concern that the citation implies that OPP had identified piperonyl butoxide as a potential respiratory allergen. Dr. Philpott proposed replacing the reference to OPP with peer-reviewed references that were included in the Newton and Breslin study regarding the allergic potential of piperonyl butoxide. He recommended that such a citation be included for the benefit of the reader who wishes to know more about piperonyl butoxide and its potential for causing allergic reactions. Dr. Philpott will incorporate this change into the meeting report.

Regarding the ethics charge question for the Newton and Breslin study, no changes were made to the Board's conclusion that the study was not fundamentally unethical or significantly deficient relative to the ethical research standards prevailing at the time the study was conducted.

**Assessment of Completed Research Study: Lisi, P. (1992) Short Communication: Sensitization risk of pyrethroid insecticides. *Contact Dermatitis* 26:349-350.**

The Board discussed its conclusions regarding the Lisi study, in which 230 volunteers were patch tested with seven pyrethroids to evaluate the irritation and sensitization potential of these chemicals.

Regarding the first charge question, the Board concluded that the Lisi study likely was scientifically sound, but limited details may have prevented a completely accurate assessment of its reliability. Dr. Philpott inquired if Board members had comments on the Board's response to the charge question. No changes were suggested.

The second charge question asked whether the study data were relevant for assessing the association between pyrethrin/pyrethroid exposure and allergic contact dermatitis or sensitization responses. The Board concluded that the study was likely to be relevant to this assessment. Dr. Philpott inquired if Board members had comments on the Board's response to the charge question. No changes were suggested.

The third charge question asked the Board to describe limitations of the Lisi study for the EPA assessment of pyrethrin/pyrethroid exposure and allergic contact dermatitis or sensitization. Dr. Popendorf stated that the third sentence in the Board's response to this charge question suggests a Board interpretation of the data that EPA did not request. The low rate of response in the study makes it difficult to determine if these are true responses and whether the sensitization rate is low or non-existent. By implying that the response is real and low, the Board may have over-interpreted the data. Dr. Janice Chambers agreed that the Board was not asked to interpret the data. Dr. Michael Lebowitz also agreed, and noted that Board was asked only to identify limitations, not to make judgments concerning risk or response rate. Dr. Philpott agreed to remove the first part of the sentence ("This may suggest that the seven compounds tested pose little risk of allergic contact dermatitis or skin sensitization but...") to address the concern that the Board may have provided an unwarranted interpretation of the data. The Board members agreed to this change.

Regarding the ethics charge question for this study, the Board acknowledged that although limited information was available, they could not conclude that the study was fundamentally unethical or conducted in an unethical manner. Dr. Popendorf pointed out a typographical error at the end of the first paragraph under HSRB Detailed Recommendations and Rationale, in which "Board" should be changed to "Board's." No further comments regarding the ethics charge were received.

**Assessment of Proposed Carroll-Loye Biological Research Study LNX-003: Efficacy Test of KBR 3023 (Picaridin; Icaridin) - Based Personal Insect Repellents (20% Cream and 20% Spray) with Ticks Under Laboratory Conditions.**

The Board reviewed the proposed Carroll-Loye Biological Research (CLBR) study LNX-003, which will test the efficacy of two formulations (spray and cream) containing 20 percent picaridin against two species of ticks in a laboratory setting.

With respect to the science charge question, the Board concluded that the tick repellency study was likely to generate scientifically reliable data useful for assessing the efficacy of the tested materials in repelling ticks. Dr. Popendorf raised a question regarding the last sentence of the last paragraph of the Board's detailed recommendations and rationale for this charge question. He asked whether complete protection time (CPT) was used for these studies because of Agency requirements, and if so, suggested that the Board clarify its suggestion that calculating the proportion of individuals protected for a given time may be a better way to report the data. Dr. Chambers clarified that EPA provides guidelines, not requirements, for these protocols. Mr. Carley agreed and clarified that the guidelines do not have the same force as a regulation. He stated that EPA understands the Board's comment regarding this matter to be a general statement that does not apply specifically to this protocol. The protocol provides CPT, which is consistent

with how EPA interprets data to be used for label claims for protection. He agreed that better ways to analyze and interpret data from these studies exist, but this matter pertains to EPA internal procedures rather than this particular protocol.

Dr. Popendorf suggested modifying the end of the sentence to, "...should be considered by the Agency." Dr. Sidney Green stated that the Board should be clear that this suggestion is not specific to this protocol. Dr. Chambers suggested that this sentence be separated into a separate paragraph, but Dr. Linda Young disagreed. She suggested adding a phrase indicating that the analysis techniques currently planned do not account for censored data, which is problematic, but the protocol is consistent with EPA guidelines. The first sentence of the paragraph implies that this suggestion applies to EPA and not specifically to this protocol. Drs. Philpott and Chambers agreed with Dr. Young's conclusion. Dr. Philpott agreed to add the phrase suggested by Dr. Popendorf to the final sentence.

Dr. Young reiterated that the lack of consideration of censoring is a major flaw to these protocols and is not addressed in the EPA guidelines. Dr. Young suggested revising the second line of the final paragraph in the section HSRB Detailed Recommendations and Rationale to read, "...the proposed statistical approach is not ideal and fails to account for censoring of the data and the calculation of complete protection time is not the best end-use of the study data." The Board members agreed to this revision.

Regarding the ethics charge question, the Board concluded that the protocol was likely to meet the applicable requirements of 40 Code of Federal Regulations (CFR) part 26, subparts K and L. Dr. Philpott conveyed a suggestion from Dr. Vanessa Northington Gamble, regarding minor changes to better summarize the ways in which Dr. Scott Carroll (CLBR) has minimized coercion of participants, particularly CLBR employees and University of California-Davis students. Some of these changes relate to clarifying references to previous reports for readers who may not have attended all HSRB meetings.

Several typographical changes were suggested by Dr. Popendorf and EPA staff. Dr. Popendorf pointed out that in the first bullet under section b, the phrase, "Study Directory" should be changed to "Study Director," and "mechanisms design" should be changed to "mechanisms designed." EPA requested Dr. Philpott change references to "insects" to "ticks," because this protocol was designed only to test efficacy of the repellants against ticks. Dr. Chambers advised that general comments about these and similar protocols should refer to "arthropods." Dr. Philpott agreed to make the suggested changes within the meeting report.

Mr. Carley clarified that the Board refers to 40 participants in the overview of the study, but the study will actually enroll only 20 subjects. Each of the two treatments will be tested on 10 subjects and each subject serves as his or her own control. Dr. Philpott agreed to check the accuracy of this statement. Mr. Carley also clarified the Board statement in the second paragraph of its detailed recommendations and rationale regarding the science charge question (page 17). CLBR has included a dosimetry phase in every protocol it has brought to the Board. Inclusion of dosimetry testing was in response to Agency guidelines, rather than Board recommendations. The Board has suggested that other groups, such as ICR, Inc., include dosimetry testing. The

Board agreed to change the final sentence of this paragraph to read, "The protocol also incorporated use of dosimetry-generated data, which will likely generate data representative of real-world use."

**Assessment of Proposed AEATF II Scenario and Protocol AEA04: Research on Exposure of Janitorial Works Applying Pesticides Formulated as Aerosol Sprays.**

The Antimicrobial Exposure Task Force II (AEATF II) protocol AEA04 proposed to measure a typical occupation handler's daily exposure to an antimicrobial spray packaged in a pressurized aerosol spray can and use these data generically to estimate dermal and inhalation exposures and risk for other antimicrobial ingredients in similar aerosol spray forms.

Regarding the science charge question, the Board expressed concerns regarding how the results would be used, whether the data could be used to assess exposure during non-professional use, adequacy of the proposed sample size and statistical analyses, and how the aerosol spray would be used. Recommendations for improving quality assurance and quality control (QA/QC) also were made.

Dr. Young suggested that in the Sample Size & Analysis section of the HSRB Detailed Recommendations and Rationale, the sentence, "Based on the information provided, a sample size of 18 participants may be sufficient," be changed to "The sample size adequacy cannot be judged without a statistical analysis plan." She also asked that the word "these" and "as well" be removed from the third sentence in this section. Dr. Philpott agreed to revise the meeting report accordingly.

Dr. Popendorf raised concerns regarding the QA/QC section of the HSRB Detailed Recommendations and Rationale. Section 4c does not clearly address the issue of possible gross deviation from the protocol. The point of this section is to address in detail how (or whether) data gathered when a participant deviates significantly from the protocol (for example, wiping after spraying or placing his hands on the newly sprayed surface) will be used. Dr. Lebowitz suggested including a statement recommending that gross deviations from the protocol will lead to rejection of the data. Dr. Popendorf suggested including in the first sentence of this section a statement indicating that when the magnitude of the exposure constitutes grounds for gross deviation from the protocol, the data gathered from this participant will be excluded, as described in the informed consent forms (ICFs). Dr. Philpott agreed with Dr. Young's suggestion to split this into two sentences and also to add a third clause to clarify that data from participants are being excluded for gross deviation from the protocol, not because of a variable that affects exposure. He clarified that a second sentence would be added to Section 4c, stating that observations during gross deviations from the protocol should be excluded from the final data set.

Regarding the ethics charge question, the Board concluded that the protocol was likely to comply with the applicable requirements of 40 CFR part 26 subparts K and L. Dr. Philpott described modifications to the draft that were proposed by Dr. Northington Gamble. These changes included explicit suggestions (e.g., references to the National Standards for Culturally and Linguistically Appropriate Services in Health developed by the Department of Health

and Human Services) for ways to make the language in the ICFs and other relevant materials more culturally appropriate. This information is provided for guidance and is not a requirement for the protocol.

Ms. Kelly Sherman (OPP, EPA) suggested minor corrections to the sixth bullet in section 1a ("Recruitment materials should state...") and the second bullet in section 1b ("...and thus might be susceptible..."). Dr. Popendorf corrected a typographical error in bullet 2 of section 1a ("... the heat index will be monitored..."). Ms. Sherman also suggested a minor editorial correction to the second bullet in section 2 ("...or the insurance of a third party under which you are covered.").

**SUMMARY AND NEXT STEPS**

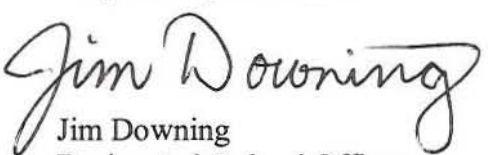
Dr. Philpott explained that he will work with Dr. Chambers and Mr. Downing to incorporate the suggestions and changes discussed during this teleconference meeting. After the changes are made, the final meeting report will be released to the public.

Dr. Philpott asked each Board member to approve or disapprove of the changes discussed during the teleconference meeting. The Board members unanimously approved the changes.

Mr. Downing informed Board members that the January 2010 HSRB meeting had been cancelled. The next Board meeting will be held April 13-16, 2010, in Arlington, Virginia.

The teleconference meeting was adjourned by the Chair.

Respectfully submitted:



Jim Downing
Designated Federal Officer
Human Studies Review Board
United States Environmental Protection Agency

Certified to be true by:

Sean Philpott, Ph.D., M.S. Bioethics
Chair
Human Studies Review Board
United States Environmental Protection Agency

NOTE AND DISCLAIMER: The minutes of this public teleconference meeting reflect diverse ideas and suggestions offered by Board members during the course of deliberations within the meeting. Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice from the Board members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final report prepared and transmitted to the EPA Science Advisor following the public meeting.

## Attachments

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|---|---|
| Attachment A | HSRB Members and Consultants |
| Attachment B | Federal Register Notice Announcing Meeting |
| Attachment C | Meeting Agenda |

**Attachment A**

**EPA HUMAN STUDIES REVIEW BOARD MEMBERS**

**Chair**

**Sean Philpott, Ph.D., M.S. Bioethics**
Director, Research Ethics
The Bioethics Program
Union Graduate College – Mt. Sinai School of Medicine
Schenectady, NY

**Vice Chair**

**Janice Chambers, Ph.D., D.A.B.T.**
William L. Giles Distinguished Professor
Director, Center for Environmental Health Sciences
College of Veterinary Medicine
Mississippi State University
Mississippi State, MS

**Members**

**Suzanne C. Fitzpatrick, Ph.D., D.A.B.T.**
Senior Science Policy Analyst
Office of the Commissioner
Office of Science and Health Coordination
U.S. Food and Drug Administration
Rockville, MD

**Vanessa Northington Gamble, M.D., Ph.D.***
University Professor of Medical Humanities
Gelman Library
The George Washington University
Washington, DC

**Sidney Green, Jr., Ph.D., Fellow, ATS**
Department of Pharmacology
Howard University College of Medicine
Howard University
Washington, DC

**Dallas E. Johnson, Ph.D.**
Professor Emeritus
Department of Statistics
Kansas State University
Manhattan, KS

**Michael D. Lebowitz, Ph.D., FCCP**
Retired Professor of Public Health (Epidemiology) and Medicine
Research Professor of Medicine
University of Arizona
Tucson, AZ

**Lois D. Lehman-McKeeman, Ph.D.**
Distinguished Research Fellow
Discovery Toxicology
Bristol-Myers Squibb Company
Princeton, NJ

**Jerry A. Menikoff, M.D.***
Director, Office of Human Research Protections
U.S. Department of Health and Human Services
Rockville, MD

**Rebecca Tyrrell Parkin, Ph.D., MPH***
Associate Dean for Research and Public Health Practice
School of Public Health and Health Services
The George Washington University
Washington, DC

**William J. Popendorf, Ph.D.**
Professor
Department of Biology
Utah State University
Logan, UT

**Ernest D. Prentice, Ph.D.***
Associate Vice Chancellor for Academic Affairs
Professor of Genetics, Cell Biology and Anatomy
Professor of Preventive and Societal Medicine
University of Nebraska Medical Center
Omaha, NE

**Linda J. Young, Ph.D.**
Department of Statistics
Institute of Food and Agricultural Sciences
University of Florida
Gainesville, FL

* Not in attendance at the December 16, 2009 Teleconference Meeting

**Attachment B**

**Federal Register Notice Announcing Meeting**

[Federal Register: December 1, 2009 (Volume 229, Number 74)]
[Notices]
[Page 62772-62773]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr01de09-57]

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**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-ORD-2009-0891; FRL-9087-9]**

**Human Studies Review Board (HSRB); Notification of a Public Teleconference to Review Its Draft Report From the October 20-21, 2009 HSRB Meeting**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

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**SUMMARY:** The EPA Human Studies Review Board (HSRB) announces a public teleconference meeting to discuss its draft HSRB report from the October 20-21, 2009 HSRB meeting.

**DATES:** The teleconference will be held on Wednesday, December 16, 2009, from 10 a.m.-12 p.m. (Eastern Time).

*Location:* The meeting will take place via telephone only.

*Meeting Access:* For information on access or services for individuals with disabilities, please contact Lu-Ann Kleibacker at least 10 business days prior to the meeting using the information under **FOR FURTHER INFORMATION CONTACT**, so that appropriate arrangements can be made.

*Procedures for Providing Public Input:* Interested members of the public may submit relevant written or oral comments for the HSRB to consider during the advisory process. Additional information concerning submission of relevant written or oral comments is provided in Unit ID of this notice.

**FOR FURTHER INFORMATION CONTACT:** Members of the public who wish to obtain the call-in number and access code to participate in the telephone conference, request a current draft copy of the Board's report or who wish further information may contact Lu-Ann Kleibacker, EPA, Office of the Science Advisor (8105R), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; or via telephone/voice mail at (202) 564-7189 or via e-mail at kleibacker.lu-ann@epa.gov. General information concerning the EPA HSRB can be found on the EPA Web site at http://www.epa.gov/osa/hsrb/.

**ADDRESSES:** Submit your written comments, identified by Docket ID No. EPA-HQ-ORD-2009-0891, by one of the following methods:

*http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

*E-mail:* ORD.Docket@epa.gov.

*Mail:* ORD Docket, Environmental Protection Agency, Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

*Hand Delivery:* EPA Docket Center (EPA/DC), Public Reading Room, Infoterra Room (Room Number 3334), EPA West Building, 1301 Constitution Avenue, NW., Washington, DC 20460, Attention Docket ID No. EPA-ORD-2009-0891. Deliveries are only accepted from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA-HQ-ORD-2009-0891. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comments include information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http://www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. If you send an e-mail comment directly to EPA, without going through http://www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet.

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## I. General Information

### *A. Does this Action Apply to Me?*

This action is directed to the public in general. This action may, however, be of interest to persons who conduct or assess human studies on substances regulated by EPA or to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

*B. How Can I Access Electronic Copies of this Document and Other Related Information?*

In addition to using regulations.gov, you may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at http://www.epa.gov/fedrgstr/.

*Docket:* All documents in the docket are listed in the index under the docket number. Even though it will be listed by title in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Copyright material, will be publicly available only in hard copy. Publicly available docket materials are electronically available either through http://www.regulations.gov or in hard copy at the ORD Docket, EPA/DC, Public Reading Room, Infoterra Room (Room Number 3334), 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the ORD Docket is (202) 566-1752.

*C. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you use that support your views.
4. Provide specific examples to illustrate your concerns and suggest alternatives.
5. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date and Federal Register citation.

*D. How May I Participate in this Meeting?*

You may participate in this meeting by following the instructions in this section. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA-HQ-ORD-2009-0891 in the subject line on the first page of your request.

1. Oral comments. Requests to present oral comments will be accepted up to Wednesday, December 9, 2009. To the extent that time permits, interested persons who have not pre-registered may be permitted by the Chair of the HSRB to present oral comments at the meeting. Each individual or group wishing to make brief oral comments to the HSRB is strongly advised to submit their request (preferably via e-mail) to Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT** no later than noon, Eastern Time, December 9, 2009, in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB DFO to review the meeting agenda to provide an appropriate public comment period. The request should identify the name of the individual making the presentation and the organization (if any) the individual will represent. Oral comments before the HSRB are limited to 5 minutes per individual or organization. Please note that this includes all individuals appearing either as part of, or on behalf of an organization. While it is our intent to hear a full range of oral comments on the science and ethics issues under discussion, it is not our intent to permit organizations to expand the time limitations by having numerous individuals sign up

separately to speak on their behalf. If additional time is available, public comments may be possible.

2. Written comments. Although you may submit written comments at any time, for the HSRB to have the best opportunity to review and consider your comments as it deliberates on its report, you should submit your comments at least 5 business days prior to the beginning of this teleconference. If you submit comments after this date, those comments will be provided to the Board members, but you should recognize that the Board members may not have adequate time to consider those comments prior to making a decision. Thus, if you plan to submit written comments, the Agency strongly encourages you to submit such comments no later than noon, Eastern Time, December 9, 2009. You should submit your comments using the instructions in Unit 1.C. of this notice. In addition, the Agency also requests that persons submitting comments directly to the docket also provide a copy of their comments to Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit on the length of written comments for consideration by the HSRB.

**E. Background**

The EPA Human Studies Review Board will be reviewing its draft report from the October 20-21, 2009, HSRB meeting. The Board may also discuss planning for future HSRB meetings. Background on the October 20-21, 2009, HSRB meeting can be found at Federal Register 74 190, 50965 (October 2, 2009) and at the HSRB Web site http://www.epa.gov/osa/hsrb/. The October 20-21, 2009 meeting draft report is now available. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the http://www.regulations.gov Web site and the HSRB Internet Home Page at http://www.epa.gov/osa/hsrb/. For questions on document availability or if you do not have access to the Internet, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: November 25, 2009.
Kevin Teichman,
Acting EPA Science Advisor.
[FR Doc. E9-28700 Filed 11-30-09; 8:45 am]

BILLING CODE 6560-50-P

**Attachment C**

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**HUMAN STUDIES REVIEW BOARD (HSRB)**
**PUBLIC TELECONFERENCE MEETING**
**DECEMBER 16, 2009**
**10:00 am - 12:00 pm (Eastern Time)***

**HSRB MEETING FOR REVIEW AND APPROVAL OF**
**DRAFT OCTOBER 20-21, 2009 HSRB MEETING REPORT**

**HSRB WEB SITE http://www.epa.gov/osa/hsrb/**
**Docket Telephone: (202) 566 1752**
**Docket Number: EPA–HQ–ORD–2009–0891**

**Meeting location via telephone only**

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| **10:00 AM** | **Convene Meeting and Identification of Board Members** – Jim Downing (Designated Federal Officer, HSRB, Office of the Science Advisor [OSA], EPA) |
| **10:10 AM** | **Meeting Administrative Procedures** – Jim Downing (DFO) |
| **10:15 AM** | **Meeting Process** – Sean Philpott, Ph.D. (HSRB Chair) |
| **10:20 AM** | **Public Comments** |
| **10:30 AM** | **Board Discussion and Decision on Final Report** – Sean Philpott, Ph.D. (HSRB Chair) |

The Board's response to EPA charge questions presented at the October 20-21, 2009 meeting.

Assessment of Completed Research Study: Newton, J., Breslin, A. (1983) Asthmatic reactions to a commonly used aerosol insect killer. Medical Journal of Australia 1:378-380.

Newton & Breslin study (1983)

Is the Newton & Breslin study scientifically sound, providing reliable data?

If so, is the Newton & Breslin study relevant to an assessment of the proposition that exposures to pyrethrins/pyrethroids may be associated with asthmatic or allergic respiratory responses?

If so, what limitations of the Newton & Breslin study should be taken into account by EPA in assessing the proposition that exposures to pyrethrins/ pyrethroids may be associated with asthmatic or allergic respiratory responses?

Is there clear and convincing evidence that the conduct of the Newton & Breslin study was fundamentally unethical, or that its conduct was significantly deficient relative to standards prevailing when it was conducted?

Assessment of Completed Research Study: Lisi, P. (1992) Short Communication: Sensitization risk of pyrethroid insecticides. Contact Dermatitis 26:349-350.

Lisi study (1992)

Is the Lisi study scientifically sound, providing reliable data?

If so, is the Lisi study relevant to an assessment of the proposition that exposures to pyrethrins/pyrethroids may be associated with allergic contact dermatitis or sensitization responses?

If so, what limitations of the Lisi study should be taken into account by EPA in assessing the proposition that exposures to pyrethrins/pyrethroids may be associated with allergic contact dermatitis or sensitization responses?

Is there clear and convincing evidence that the conduct of the Lisi study was fundamentally unethical, or significantly deficient relative to the standards of ethical research conduct prevailing when it was conducted?

Assessment of Proposed AEATF II Scenario and Protocol AEA04: Research on Exposure of Janitorial Works Applying Pesticides Formulated as Aerosol Sprays.

If the proposed AEATF-II aerosol application scenario and field study protocol AEA04 is revised as suggested in EPA's review and if the research is performed as described:

1. Is the research likely to generate scientifically reliable data, useful for assessing the exposure of handlers who apply antimicrobial pesticides formulated as aerosol sprays?

2. Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

Assessment of Proposed Carroll-Loye Biological Research Study LNX-003: Efficacy Test of KBR 3023 (Picaridin; Icaridin) - Based Personal Insect Repellents (20% Cream and 20% Spray) with Ticks Under Laboratory Conditions.

If the proposed laboratory tick repellency study protocol LNX-003 is revised as suggested in EPA's review and if the research is performed as described:

1. Is the research likely to generate scientifically reliable data, useful for assessing the efficacy of the tested materials in repelling ticks?

2. Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

**11:55 AM** **Summary and Next Steps** – Sean Philpott, Ph.D. (HSRB Chair) and Jim Downing (DFO)

**12:00 PM Adjournment**

* Please be advised that agenda times are approximate. For further information, please contact the Designated Federal Officer for this meeting, Jim Downing via telephone: (202) 564-2468 or email: downing.jim@epa.gov.